

## REMARKS/ARGUMENTS

This amendment is filed in response to the office action mailed February 4, 2008. A petition for a one month extension of time is submitted herewith. Applicants thank Examiner for the courtesy shown to the Attorney, Karen Harding, during the June 4 teleconference.

### Rejections under 35 U.S.C. 103(a)

Examiner has rejected claims 1-3, 5-8, 14-20, 23, 31, 32, 34-38, and 52-87 under 35 U.S.C. 103(a) as being unpatentable over Muir et al. (WO 00/04078; published January 27, 2000) in view of either Mueller et al. (EP 362137) or Vanderlaan et al. (US 6,087,415) and in view of Martin et al (US6,039,899).

Claims 1, 14 and 31 have been amended to recite that the coating composition does not chemically attach to the lens. Support for this amendment may be found at page 2, lines 16-18 of the present application.

All references to Muir et al. are to the US counterpart, US 6,893,595. Muir et al. discloses “coating a mold with a *reactive* polymer, a liquid curable composition is filled in to the mold and cured under conditions *such that the reactive polymer becomes covalently bonded to the cured bulk mold material at the interface.*” Muir et al. abstract (emphasis added). Muir et al. does not disclose that the polymers which are recited in amended claim 1, and claims 14 and 21 could be used in a coating solution. Instead, Muir et al. discloses in Example 15, column 31, lines 40-43, that HEMA, a **monomer**, may be included in the coating solution. Muir et al. also does not disclose a dwell time of less than about 5 minutes or less than about 45 seconds.

Meuller et al. discloses polymer composite articles formed via transfer-grafting. See the abstract (“Polymer composites are described which consist of . . . a prehsaped, surface-forming hydrophilic fist polymer A covalently grafted onto an underlaying bulk and structural second polymer”), the description of Polymer A (page 4, line 40-page 5, line 3). While water soluble monomers, such as hydroxyethyl methacrylate may be comonomers, monomers with functional groups which are coreactive with the substrate polymer must also be included. The underlaying polymer B-1, must also contain reactive groups capable of reacting with those in the A-1 polymers. See page 7, lines 38-40 of Meuller et al. Meuller et al. is silent with respect to the desirability of a dwell time, let alone the dwell times recited in the present claims.

Vanderlaan et al. discloses “contacting at least one surface of a medical device with a coating effective amount of a carboxyl-functional polymer and . . . at least *one coupling agent*”. Column 1, lines 39-42. One or more surfaces of a device may be coated using the process of

disclosed in Vanderlaan et al.. Vanderlaan et al., column 2, lines 38-39 (emphasis added). Preparation 1, column 6, lines 1-10, discloses making an uncoated silicone hydrogel contact lens, which is then coated by contacting the formed lens with a coating solution and a coupling agent (Example 1). Vanderlaan et al. neither discloses nor suggests

- (a) coating compositions which do not chemically attach to the substrate,
- (b) coating a molding surface with a high molecular weight coating composition;
- (c) dispensing a monomer mixture comprising, a silicone-containing hydrogel monomer, into the mold or mold half; and
- (d) curing the monomer mixture and the coating composition using a dwell time of less than about 5 minutes and under conditions suitable to form an article coated with the coating composition.

Martin et al. discloses an apparatus and process for making contact lenses. Martin et al. discloses suitable time for injection molding of the contact lens molds at col. 10, lines 60-67, discloses a precure for a unitary lens at col. 32, lines 28-41 and discloses clamping and cure time at col. 35, lines 30-33. Martin et al. does not disclose process conditions for curing a lens with a high molecular weight coating composition included on the lens mold surface.

Accordingly none of the references suggest or disclose a process which coats a lens with high molecular weight coating composition which does not chemically attach to the lens.

Present claims 6, 7, 18, 31 and 32-41 further recite that the dwell time prior to curing be less than about 45 seconds, to insure that the lens coating is not dissolved by the monomer mixture.

Martin et al. also discloses

“Accumulator section 168 includes a holding mechanism 166 that is timed by a control means (not shown) to halt a lead pallet in place on the conveyor 32(c) and enable a predetermined number of subsequent pallets to assemble behind the halted lead pallet to enable batch processing at the procure apparatus. In the preferred embodiment, twelve pallets are accumulated enabling up to ninety-six (96) mold assemblies to be processed at the precure apparatus 60 in a batch mode for an extended period of time of 30 to 60 seconds while continuously receiving new pallets from the production line at a rate of 1 every 6 to 12 seconds.” Column 32, lines 51-65.

Accordingly to Martin et al. the accumulator holds new pallets until 12 are accumulated. If pallets

arrive every 6 to 12 seconds, that means the lenses can be held at the accumulator from between 72 to 144 seconds . Applicants respectfully submit that Martin et al. does not disclose or suggest that a dwell time of less than 45 seconds is desirable when curing lens reactive mixtures comprising a high molecular weight polymer coating.

None of the references cited by Examiner disclose or suggest high molecular weight polymer coatings which do not chemically attach to the lens, or that dwell time as recited in the present claims are desirable. It is not obvious from the references cited that the coating composition would be soluble in the hydrogel, nor that utilizing the disclosed dwell time would be desirable.

None of the references cited by the Examiner disclose or suggest the coating composition solvents used in combination with the high molecular weight coatings which are recited in the present claims.

Applicants respectfully submit that claims 1, 14 and 31 as amended, and claims 2-3, 5-8, 15-20, 23, 32, 34-38, and 52-87 which depend therefrom are patentable over Muir et al. in view of either Meuller et al. or Vanderlaan et al. and in view of Martin et al. Withdrawal of the rejection is requested.

Examiner has further rejected claims 9, 10, 24, 25, 39 and 40 under 35 U.S.C. 103(a) as unpatentable over Muir et al. in view of either Meuller et al. or Vanderlaan et al. and in view of Martin et al. in view of Li et al. (US6,565,776).

Li et al. discloses “using inorganic material to coat the optical surfaces and sidewalls of mold parts made from clear-resin materials”. The coating materials protect “the clear resin from interaction with otherwise reactive monomers from which the molded article is made, such coatings can also be used to achieve preferential release. Li et al. abstract. Thus the coatings of Li et al. remain on the lens mold and do not become part of the contact lens. Li et al. discloses neither processes for making coated contact lenses, nor the recited dwell times. Thus, Li et al. does not cure the deficiencies of the previously discussed references.

Examiner has further rejected claims 11, 26 and 41 under 35 U.S.C. 103(a) as unpatentable over Muir et al. in view of either Meuller et al. or Vanderlaan et al. and in view of Martin et al. in view of Soye et al. (US5,316,700). Claim 11 depends indirectly from claim 1, which, as amended, recites that the polymer does not chemically attach to the lens. Claim 26 depends indirectly from claim 14, which as amended, recites that the coating composition does not chemically attach to the lens. Claim 41 depends indirectly from claim 31, which recites a

45 second dwell time and as amended, recites that the coating composition does not chemically attach to the lens.

Soye et al. et al discloses “providing [a] cavity for excess lens forming material with at least two openings and producing differential gas pressure across the opening to remove excess lens forming material.” Soye et al. abstract. Soye et al. does not disclose methods for forming coated contact lenses, or dwell times useful therefore. Thus, Soye et al. does not cure the deficiencies of the previously discussed references.

Examiner has further rejected claims 19, 20, 34 and 35 under 35 U.S.C. 103(a) as unpatentable over Muir et al. in view of either Meuller et al. or Vanderlaan et al. and in view of Martin et in view of Turner et al. (US6,565,776).

Turner et al discloses coating a hydrophobic lens substrate “with a hydrophilic material having an expansion factor greater than one.” Turner neither discloses nor suggests coating compositions comprising high molecular weight polymers which do not chemically attach to the lens, nor a dwell time of less than 5 minutes or 45 seconds as recited in the present claims. Thus, Turner et al. does not cure the deficiencies of the previously discussed references.

#### **Conclusions**

Applicants respectfully submit that the foregoing arguments and amendments have traversed the Examiner’s rejections. Withdrawal of the rejections and allowance of the claims as amended is respectfully requested. If the Examiner is of a contrary view, the Examiner is requested to contact the undersigned attorney at (904) 443-3074.

Respectfully submitted,

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